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09/887,182	06/22/2001	Chandra Vargeese	MBHB00-830-A; 600/005	8596

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MCDONNELL BOEHNNEN HULBERT & BERGHOFF  
300 SOUTH WACKER DRIVE  
SUITE 3200  
CHICAGO, IL 60606

EXAMINER

YOUNG, JOSEPHINE

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/17/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/887,182

Applicant(s)

VARGESE ET AL.

Examiner

Josephine Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 2,4-7,9,11,13-18,23-37,39,41,42,44,45 and 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,8,10,12,19-22,38,40,43 and 46 is/are rejected.
- 7) ☒ Claim(s) 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I in Paper No. 12, filed April 1, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 2, 4-7, 9, 11, 13-18, 23-37, 39, 41, 42, 44, 45 and 47-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

An action on the merits on claims 1, 3, 8, 10, 12, 19-22, 38, 40, 43 and 46 is contained herein.

### ***Priority***

The disclosure is objected to because of the following informalities: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Therefore, the relationship between the applications and USSN 09/178,154

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must be provided. Further, the current status of all nonprovisional parent applications referenced should be included.

Appropriate correction is required.

### ***Claim Objections***

Claims 21-22 are objected to because of the following informalities: The claim recites the following limitations on the loading capacity based on micrograms of linker/terminal chemical group per gram of solid support using the abbreviation umol/gram. However, the more accepted abbreviation is  $\mu\text{mol}$ /gram.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 10, 12, 19-22, 38, 43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "terminal chemical group" renders the claims in which it appears indefinite. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*,

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190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “terminal chemical group” in claim 1 is used by the claim to mean a chemical entity from which an oligonucleotide can be synthesized (page 19, lines 1-7), while the accepted meaning is much broader in scope and can be construed as any chemical entity. The term is indefinite because the specification does not clearly redefine the term.

The term “succinate derivative” in claim 8 renders the claims in which it appears indefinite. In the absence of the specific modification to the succinate or distinct language to describe the structural modifications or the chemical names of the succinate derivative of this invention, the identity of said succinate derivative would be difficult to describe and the metes and bounds of said succinate derivative that Applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method steps do not clearly set forth the conditions that are necessary for isolation of the compound of claim 3, i.e. the compound of the formula V(a).

Similarly, claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method steps do not clearly set forth the conditions that are necessary for isolation of the compound of claim 1, i.e. the compound of the formula I.

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The term “abasic succinate” in claim 43 renders the claim indefinite. It is unclear as to how succinate can be abasic, as succinate does not contain a basic moiety.

Claims 8 and 46 are rejected under 35 U.S.C. 112 for being vague and indefinite. It is unclear as to if the recitation of “a nucleic acid, nucleoside, nucleotide, or non-nucleoside succinate derivative” and “adenosine, cytidine, guanosine, thymidine, or uridine succinate”, respectively, should be interpreted to mean “a nucleic acid succinate derivative, nucleoside succinate derivative, nucleotide succinate derivative, or non-nucleoside succinate derivative” and “adenosine succinate, cytidine succinate, guanosine succinate, thymidine succinate, or uridine succinate”, respectively. Alternatively, the claims could be interpreted in such a way that only the non-nucleoside and uridine, respectively, are derivatized with succinate.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 19 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by the patent US 5,002,884 to KOBAYASHI et al. (A)

KOBAYASHI teaches physiologically active substances that are immobilized on an inorganic support, by treating the inorganic support with an aminoalkylalkoxysilane. See Abstract. In column 1, lines 55-58, KOBAYASHI discloses that the inorganic carrier or support can be porous glass, silica gel, colloidal silica, alumina, etc. KOBAYASHI teaches in column 1,

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lines 59-64, that the aminoalkylalkoxysilane used to treat the inorganic carriers can be N-(6-aminohexyl)-3-aminopropyltrimethoxysilane.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 8, 10, 12, 19-22, 38, 40, 43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over KOBAYASHI (A) and the patent US 5,141,813 to NELSON (citation no. 11, paper no. 7, IDS Form 1449, filed April 4, 2002).

Applicant claims chemical entities from which oligonucleotides can be synthesized (B), for example nucleic acids, nucleosides, or nucleotides, and in particular entities with an acid labile protecting group such as trityl groups, linked via a N-(6-aminohexyl)-3-aminopropyldimethoxysilane linker to a solid support (SP), such as controlled pore glass (CPG). Applicant further claims methods to make such compounds, including methods that specify the

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loading capacity of the solid support, namely from about 50 to about 100  $\mu\text{mol/gram}$  of solid support, or from about 75 to about 85  $\mu\text{mol/gram}$  of solid support.

As set forth supra, KOBAYASHI teaches physiologically active substances that are immobilized on an inorganic support, by treating the inorganic support with an aminoalkylalkoxysilane. See Abstract. In column 1, lines 55-58, KOBAYASHI discloses that the inorganic carrier or support can be porous glass, silica gel, colloidal silica, alumina, etc. KOBAYASHI teaches in column 1, lines 59-64, that the aminoalkylalkoxysilane used to treat the inorganic carriers can be N-(6-aminohexyl)-3-aminopropyltrimethoxysilane.

Further, KOBAYASHI discloses that “the aminopropylalkoxysilane mediates chemical bonding between the inorganic carrier or support and the physiologically active substance” (column 2, lines 26-29).

KOBAYASHI does not explicitly teach that the physiologically active substance can be a nucleoside, nucleotide or a chemical entity from which an oligonucleotide can be synthesized. Further, KOBAYASHI may not distinctly disclose the loading capacity of the solid support.

NELSON teaches novel multifunctional solid support reagents that are useful in solid phase oligonucleotide synthesis. See Abstract. In column 2, lines 35-44, NELSON discloses that the reagent is linked to a solid such as controlled pore glass (CPG [CPG Biosupport, Inc., Fairfield, NJ]), alkylamine CPG, etc. NELSON teaches in column 4, lines 1-11, that the oligonucleotides can be linked to the solid support via an alkoxysilane linker, namely MF-CPG®, depicted in Figure 1.

It would have been obvious to one of ordinary skill in the art to use any chemical entity from which an oligonucleotide can be synthesized, for example a nucleic acid, nucleoside, or



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nucleotide, including entities with acid labile protecting groups such as trityl groups, as the physiologically active substance immobilized on an aminoalkylalkoxysilane treated inorganic support, as per KOBAYASHI. A skilled artisan would have been motivated and have had a reasonable expectation of success to adapt the aminopropylalkoxysilane linker of KOBAYASHI to mediate chemical bonding between the inorganic carrier or support and the physiologically active substance for use in oligonucleotide synthesis as the prior art is replete with examples of solid phase oligonucleotide synthesis using solid support reagents with an alkoxysilane linker (see NELSON). Further, the particular chemical entity from which an oligonucleotide can be synthesized, as well as the loading capacity of the solid support are seen as a choice of experimental design based on the desired oligonucleotide to be synthesized and the properties of the solid support, and considered well within the purview of the prior art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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***Conclusion***

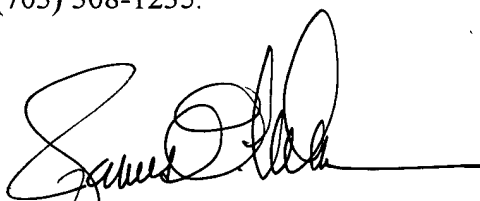
Claims 1-53 are pending. Claims 1, 3, 8, 10, 12, 19-22, 38, 40, 43 and 46 are rejected. Claims 21 and 22 are objected to. Claims 2, 4-7, 9, 11, 13-18, 23-37, 39, 41, 42, 44, 45 and 47-53 are withdrawn. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY  
June 15, 2003

  
JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600